REMARKS

By this Amendment the specification has been amended to include topic headings and the claims have been revised to better comply with U.S. practice. Entry is requested.

In the outstanding Office Action the examiner has rejected claims 17-20, 22, 24-28, 31 and 33-35 under 35 U.S.C. 102(b) as being anticipated by Wesseling. The examiner refers to claim 18 in this patent.

The applicants assert that this rejection is incorrect.

Wesseling discloses a plethysmograph pressure correcting pressure cuff and is well-known to the present inventors (see specification paragraphs [0005], [0016] and [0035] in the published version of this application, U.S. 2007/0032729 A1). Claim 18 of Wesseling describes a plethysmographic arrangement for the continuous non-invasive measurement of blood pressure (BP) including:

- a plethysmograph in a fluid-filled pressure cuff
- an electric pressure connected to the cuff
- an electronic control circuit connected to the plethysmograph provided with
    - a control loop having a differential amplifier
    - a memory circuit in the feedback circuit for the servo-reference level
    - a control loop having a PID circuit
- a parallel circuit of peak and through detector connected and responsive to the pressure signal (over a pressure transducer)

- and a state switch (s1) for closed-open loop operation

comprising:

- a conversion circuit detecting peak and/or through of the pressure signal and deriving an intermediate value from the peak and/or through amplitude of the pressure in closed loop operation

- and a timing circuit which switches the state-switch from closed-loop position to open-loop position, in which interval

  - o the intermediate value is supplied via the state switch to the electric pressure valve
  - o and the memory circuit which adjusts the servo-reference such that the difference at the differential amplifier is zero.

As can be seen from claim 18 (and all other independent claims and the description of Wesseling), this patent describes a device and a method for continuous non-invasive BP measurement where a state-switch (s1) and an associated timing circuit switches between so-called closed-loop and open-loop operation of the device. The apparatus determines a servo reference level during open loop operation (col. 5, line 4 et seq.). This servo reference level is stored into the memory 35 and acts as set-point for the PID-control circuit 8 (col. 4, line 65).

From time-to-time the state switch s1 changes back to open loop operation and the disclosed mechanism is adapting the servo reference level in memory 35.

For the storing in memory 35, the average plethysmographic signal during open loop operation at amplifier 29 is compared with the output of memory (preferable integrator) 35 until the average difference at differential amplifier 32 is zero (col. 5, line 4 et seq.). In order to obtain the pressure signal applied to the pressure valve 10 during this open loop operation, a parallel circuit containing peak 84 and through 83 detector is used. <u>This parallel circuit is used solely for this open loop mechanism</u>, whereas its pressure signal from conversion circuit 85 is applied over state switch s1.

Continuous blood pressure can only be measured during '<u>closed-loop' operation</u>. For this active closed-loop operation, the automated servo reference level in memory 35 acts according to the adjustment means 13 disclosed in prior art (Fig. 1, col. 3, line 34 et seq.) of Wesseling. <u>During this closed loop operation the memory 35 is passive – it is only actively adjusted during open loop operation</u>.

Thus, during closed loop operation, Wesseling acts according to well known "Vascular Unloading Technique" or "Penaz principle" described in paragraph [0002] of present application or in Fig. 1 of the '940 patent having only one control loop. For a long-term operation, the continuous measurement must be interrupted (e.g., every 70 heart beats) and the memory 35 must be adjusted accordingly. This disadvantages are well known and have been described in paragraphs [0016] and [0035] of the present application.

This is one of the major differences relative to the claimed invention. As described in paragraph [0007] of present application, all prior art methods relating to "Penaz' principle" have only one single control loop (e.g., PID) for closed-loop operation. This single control loop has to deal with different disturbances described in paragraphs [0008] to [0014] of the patent application.

In order to enhance the performance of the closed-loop operation, the invention describes concentric interlocking loop which are related to specific disturbances. Fast disturbances (e.g., pressure generation) are related to the inner interlocking loops whereas slower disturbances (e.g., vasodilation or vasoconstriction of the vessels) are handled by outlying loops. Thus, the present invention describes only active closed-loop operation, as a complicated open loop operation is not necessary anymore. The functionality which is described by the '940 patent is now integrated (in a completely different way) into the interlocking loops. This has the advantage that the inventive mechanism does not interrupt the measurement anymore.

Further, there is no need for a state switch s1 anymore – the underlined paragraph of claim 18: "a state switch (s1) for closed-open loop operation" does not appear in the inventive device. The control loops are closed by the amplification unit 17, which computes and adjusts P, I, and D for the underlying PID control loop (see paragraph [0068]).

In independent method and device claims 17 and 25 the innermost control loop for controlling pressure is claimed. Contrary to Wesseling, this control loop is only responsible for the actual cuff pressure. This actual cuff pressure (BP) is measured with the pressure sensor 7 and this signal is compared with the actual set-point (SW) calculated from the outlying loops. If there is a deviation between SW and BP, the differential amplifier adjusts its output and valve input (AS) until both pressure values SW and BP are equal. This enables a quasi-ideal pressure behavior for the outlying loops, as the next loop (e.g., the PID loop) is not responsible for pump-, valve-, and pressure-disturbances anymore.

As such, the examiner's anticipation rejection based on Wesseling should be withdrawn.

The examiner has rejected claims 21 and 23 under 35 U.S.C. 103(a) as being unpatentable over Wesseling in view of Korhonen, he has rejected claim 29 under 35 U.S.C. 103(a) as being unpatentable over Wesseling in view of Hatschek, he has rejected claim 30 under 35 U.S.C. 103(a) as being unpatentable over Wesseling in view of Lichowsky, and he has rejected claim 32 under 35 U.S.C. 103(a) as being unpatentable over Wesseling in view of Asada et al.

However, none of the secondary patents can overcome the noted deficiencies in Wesseling in teaching the invention of claim 17 (the open/closed loop behavior of Wesseling... Wesseling determines its values in open loop operation, not closed loop operation).

The examiner's rejections should be withdrawn and the presented claims allowed.

Respectfully submitted,

DYKEMA GOSSETT PLLC

By: ______________________

Richard H. Tushin
Registration No. 27,297
Franklin Square, Third Floor West
1300 I Street, N.W.
Washington, DC 20005-3353
(202) 906-8680